II. REMARKS

Before the amendments made herein, claims 1, 7, 17 and 22 were pending. Claims 85 to 92 have been added herein. Accordingly, after the amendments made herein are entered, claims 1, 7, 17, 22 and 85 to 92 will be pending.

A. Regarding the amendments

Claim 1 has been amended so as to be directed to a method of identifying a hair growth inducer. The amendment is supported in the specification, for example, at page 14, line 22. Claim 1, as well as claim 17, has also been amended to more clearly indicate that the molecule to be identified specifically binds to P-cadherin. The amendment is supported in the specification, for example, at page 14, lines 16-20.

New claims 85 to 90 are directed to where the inducer or inhibitor is for a human and, more specifically, a man or a woman. The amendment is supported in the specification, for example, at page 1, lines 22-26, and page 13, line 22.

New claims 91 and 92 are directed to molecules that are antisense oligonucleotides or antibodies. The amendment is supported in the specification, for example, at page 16, line 11 to page 17, line 10, and page 29, lines 3-5.

Because the amendments made herein are fully supported by the specification, no issue of new matter arises.

B. Regarding finality of the action

The Office Action Summary indicates that the Action is final. However, the substance of the Action gives no such indication. Moreover, a request for continued examination was filed and accepted with the previous response, thus removing the finality of the previous Action. Accordingly, there is no basis for making the current Action final. Appropriate correction is requested.

C. Regarding written description

Claims 1, 7, 17 and 22 are rejected as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

The Action alleges that the specification "is devoid of a description of a method to identify [a] claimed peptide molecule that is the modulator for P-Cadherin or [an] inhibitor for hair growth." Applicants respectfully disagree with this allegation.

As disclosed in the specification, a given candidate molecule, such as an antibody or an antisense oligonucleotide, can be contacted with P-Cadherin and then the P-Cadherin can be tested for inhibition or a decrease in P-Cadherin expression can be assessed. Alternatively, a candidate molecule can be introduced and then P-Cadherin enhancement or increased P-Cadherin expression can be assessed. See page 15, lines 16-23.

More specifically: "There are numerous [ways] for testing P-Cadherin function. Several assays are known for monitoring P-cadherin function, such as binding β-catenin and/or other cellular skeleton components. These assays include immunoprecipitation of cell extracts with an anti-Pcadherin antibody and immunoblotting of this reaction products to reveal a 116kD band representing P-cadherin as well as three smaller bands corresponding in decreasing size order to α-, β-, γ-catenins; microscopic examination of cell cultures in the presence of anti-E cadherin in which further inhibition of P-cadherin function leads to cell-cell interaction disruption and inhibition of keratinocyte differentiation; inhibition of actin cytoskeleton formation under changing Ca^{++} concentrations in keratinocyte cell-cultures (Lewis, J.E., Jensen, P.J. & Wheelock, M.J *J. Invest. Dermatol.* **102**, 870-877 (1994)). Specification, page 16, lines 1-11. Further, assessing an increase or decrease of P-Cadherin expression is taught in the specification and is well known in the art. See page 49, lines 6-8, for example.

Furthermore, the specification teaches ways of making anti-P-Cadherin antibodies, including using specific peptides (SEQ ID NOS:40 to 45) that are unique to P-Cadherin as opposed to other cadherins. See specification at page 11-24. The specification also contains further disclosure for making such antibodies. See page 29, line 15 to page 30, line 27.

In addition, the specification discloses several other ways of identifying peptides or proteins that bind with P-Cadherin. See for example the yeast-based two hybrid system (page 32, line 20 to page 33, line 23), the prokaryote two-hybrid system (page 33, line 24 to page 34, line 2) and using a phage display library (page 33, lines 3-11). Other forms of modulators, such as antisense molecules, are also disclosed including specific candidates likely to be inhibitors. See page 16, line 11 to page 17, line 10 and SEQ ID NOS:21-39.

Most importantly, it is essential to remember that the subject claims are directed to **identifying** P-Cadherin modulators. The subject claims are **not** directed to P-Cadherin modulators themselves. If the claims were so directed, Applicants would better understand the Action's underlying reasoning.

However, not being so directed, but rather being directed to methods of identifying modulators **not yet known** by the very definition and purpose of the claimed methods, the Action's citation of the MPEP and case law is simply not relevant.

For example, the Action sites §2163 of the MPEP regarding describing a biomolecule by functional characteristic. However, this section is directed to claiming a composition comprising or consisting of such a molecule or a method of using such a molecule. This section is not directed to methods identifying such a molecule. And if the structural characteristics of the molecule in question were known, there would be no need or point in a method to identify the molecule!

Similarly, the case law cited in the Action is simply not on point. None of these cases deals with methods of identifying the molecule in question.

In summary, the skilled artisan would know how to test a candidate molecule to see if it can function as a P-Cadherin inducer or inhibitor. As outlined above, the specification gives numerous examples and guidance of how to do this. Thus, the written description requirement is fulfilled. For these reasons, Applicants respectfully request that this rejection be withdrawn.

D. Regarding enablement

Claims 1, 7, 17 and 22 are rejected as allegedly not enabled by the specification. Applicants respectfully traverse the rejection.

The Action alleges that the specification "gives a detailed disclosure about a method to identify a peptide molecule that is a modulator . . . of P-Cadherin." However, the Action also alleges that "the description does not clearly and concisely describe a method to identify said peptide molecule, wherein said method will be to identify directly a P-Cadherin modulator." Applicants are confused by the Action's two statements.

In any event, the specification teaches numerous ways of carrying out the claimed invention. As disclosed in the specification, a given candidate molecule, such as an antibody or an antisense oligonucleotide, can be contacted with P-Cadherin and then the P-Cadherin can be tested for inhibition or a decrease in P-Cadherin expression can be assessed. Alternatively, a candidate molecule can be introduced and then P-Cadherin enhancement or increased P-Cadherin expression can be assessed. See page 15, lines 16-23.

More specifically: "There are numerous [ways] for testing P-Cadherin function. Several assays are known for monitoring P-cadherin function, such as binding β-catenin and/or other cellular skeleton components. These assays include immunoprecipitation of cell extracts with an anti-Pcadherin antibody and immunoblotting of this reaction products to reveal a 116kD band representing P-cadherin as well as three smaller bands corresponding in decreasing size order to α-, β-, γ-catenins; microscopic examination of cell cultures in the presence of anti-E cadherin in which further inhibition of P-cadherin function leads to cell-cell interaction disruption and inhibition of keratinocyte differentiation; inhibition of actin cytoskeleton formation under changing Ca^{++} concentrations in keratinocyte cell-cultures (Lewis, J.E., Jensen, P.J. & Wheelock, M.J *J. Invest. Dermatol.* **102**, 870-877 (1994)). Specification, page 16, lines 1-11. Further, assessing an increase or decrease of P-Cadherin expression is taught in the specification and is well known in the art. See page 49, lines 6-8, for example.

Furthermore, the specification teaches ways of making anti-P-Cadherin antibodies, including using specific peptides (SEQ ID NOS:40 to 45) that are unique to P-Cadherin as opposed to other cadherins. See specification at page 11-24. The specification also contains further disclosure for making such antibodies. See page 29, line 15 to page 30, line 27.

In addition, the specification discloses several other ways of identifying peptides or proteins that bind with P-Cadherin. See for example the yeast-based two hybrid system (page 32, line 20 to page 33, line 23), the prokaryote two-hybrid system (page 33, line 24 to page 34, line 2) and using a phage display library (page 33, lines 3-11). Other forms of modulators, such as antisense molecules, are also disclosed including specific candidates likely to be inhibitors. See page 16, line 11 to page 17, line 10 and SEQ ID NOS:21-39.

Finally, the Action alleges that information on one candidate molecule may not be extrapolated because biological responses are unpredictable. However, this is not relevant to the subject claims, which merely require that the candidate molecule be tested to modulate P-Cadhedrin and then be tested as a hair growth modulator.

For these reasons, Applicants respectfully request that this rejection be withdrawn.

E. Regarding indefiniteness

Claims 1, 7, 17 and 22 are rejected as allegedly indefinite, specifically, for recitation of the word "capable." Applicants respectfully traverse the rejection.

The claims have been amended herein to more clearly indicate that the recited molecule induces (claim 1) or inhibits (claim 17) P-Cadherin. Accordingly, Applicants respectfully request that this rejection be withdrawn.

F. Regarding obviousness

Claims 1, 7, 17 and 22 are rejected as allegedly over Hirai et al. in view of Brenner et al. Applicants respectfully traverse the rejection.

The Action alleges that "both Hirai et al and Brenner et al. teach methods to identify a peptide molecule that is [a] modulator of P-Cadherin, wherein said P-Cadherin inhibitor is a hair follicle and Brenner et al. teach an assay method to screen for a peptide molecule that is a modulator, i.e., inhibitor of P-Cadherin."

As an initial matter, claim 1 has been amended herein so as to be directed to a hair growth inducer. Accordingly, claim 1, and claims dependent thereon, is clearly unobvious in view of the cited references.

In addition, Applicants respectfully take issue with the Action's assertion that "Brenner et al. teach an assay method to screen for a peptide molecule that is a modulator, i.e., inhibitor of P-Cadherin." Brenner does not deal with P-Cadherin at all, but rather Cadherin 11. The difference between these two molecules is so significant that a teaching regarding one provides no teaching or motivation regarding the other.

For example, cadherin 11 is so distinct from P-Cadherin that cadherin 11 is not even expressed by hair follicle cells (or epithelial cells) but rather by mesenchymal cells. See, for example, Mol Biol Cell, 15:4310-20 (2004); Anat Rec A Discov Mol Cell Evol Biol, 270:97-102 (2003). Indeed, the absence of cadherin 11 was found not to affect hair growth but, rather, to cause a decrease in bone density and abnormality in the structure of the joint synovial lining. See J Bone Miner Res, 16:1265-71 (2001); Science, 315:1006-10 (2007).

Thus, the teaching of Brenner has no relevance whatsoever. The skilled artisan would have no more motivation to perform the claimed invention from a teaching of screening cadherin 11 inhibitors that he would from a teaching of screening for inhbitors of any other protein. Moreover, Hirai provides no teaching or even suggestion of methods for screening for hair growth inhibitors. Accordingly, a prima facie case of obviousness has not been made.

In addition, the teaching of Hirai pertains to cells of 13-day old embryos. See, for example, second paragraph of page 272 of Hirai. There is no teaching or suggestion that this would apply to adult hair follicles. In this regard, Applicants point out that newly added claims 85 to 90 are directed to non-embryos (i.e., humans), with new claims 86, 87, 89 and 90 directed to adults (i.e., men or women).

For all these reasons, Applicants respectfully request that this rejection be withdrawn.

III. CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,

Martin D. Moynihan

Martin D. Moynihan,
Registration Number 40,338

Date: August 9, 2007

Enclosed:
Petition for Extension (1 Month); and
Additional Claim Transmittal.